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Actelion Pharmaceuticals Ltd*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ACTELION PHARMACEUTICALS LTD,

Plaintiff,

v.

ZYDUS PHARMACEUTICALS (USA) INC.
and AMNEAL PHARMACEUTICALS LLC,

Defendants.

Civil Action No. 18-1397 (FLW)(LHG)
(Filed Electronically)

CONSENT JUDGMENT

Actelion Pharmaceuticals Ltd (hereinafter “Actelion”) and Zydus Pharmaceuticals (USA) Inc. (hereinafter “Zydus”), parties in the above-captioned action, have resolved this litigation for good cause and valuable consideration recognized by Actelion and Zydus. Now the parties, by their respective undersigned attorneys, hereby stipulate and consent to entry of judgment and an injunction in the action, as follows:

IT IS this 22nd day of September, 2020:

ORDERED, ADJUDGED AND DECREED as follows:

1. This District Court has jurisdiction over the subject matter of the above action and has personal jurisdiction over the parties.

2. As used in this Consent Judgment, (i) the term “Zydus Product” shall mean the drug product sold, offered for sale or distributed pursuant to Abbreviated New Drug Application No. 211224 (including any supplements or amendments thereto or replacements thereof); (ii) the term “Licensed Patent” shall mean United States Patent Number 7,094,781; and (iii) the term “Affiliate” shall mean any entity or person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with Zydus; for purposes of this definition, “control” means (a) ownership, directly or through one or more intermediaries, of (1) more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or (2) more than fifty percent (50%) of the equity interests in the case of any other type of legal entity or status as a general partner in any partnership, or (b) any other arrangement whereby an entity or person has the right to elect a majority of the Board of Directors or equivalent governing body of a corporation or other entity or the right to direct the management and policies of a corporation or other entity.

3. Zydus admits that the claims of the Licensed Patent are valid and enforceable with respect to products containing macitentan as the sole active ingredient that are sold, offered for sale or distributed under an Abbreviated New Drug Application that refers to the product sold pursuant to NDA No. 204410 as the reference-listed drug, and that the claims of the Licensed Patent would be infringed by the commercial manufacture, use, sale, offer for sale, or importation of the Zydus Product in the United States prior to expiration of the Licensed Patent.

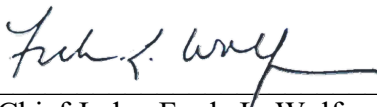
4. Unless otherwise specifically authorized by Actelion, Zydus, including any of its Affiliates, successors and assigns, is enjoined from infringing the Licensed Patent, on its own part or through any Affiliate, by making, having made, using, selling, offering to sell, importing or distributing of the Zydus Product in the United States.

5. Compliance with this Consent Judgment may be enforced by Actelion and its successors in interest, or assigns, as agreed by the parties.

6. This District Court retains jurisdiction to enforce or supervise performance under this Consent Judgment.

7. All claims, counterclaims, affirmative defenses and demands in this action are hereby dismissed with prejudice and without costs, disbursements or attorneys' fees to any party.

8. Nothing herein shall prohibit or restrict Zydus from maintaining or filing Paragraph IV certifications in Zydus's ANDA No. 211224 (including any supplements or amendments thereto or replacements thereof) under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (as amended or supplemented) and nothing herein shall prohibit or restrict the Food and Drug Administration from reviewing or approving Zydus's ANDA No. 211224 (including any supplements or amendments thereto or replacements thereof). Each party acknowledges and agrees that the 30-month stay with respect to the approval of Zydus's ANDA No. 211224 under 21 U.S.C. § 355(j)(5)(B)(iii) is hereby terminated.



Chief Judge Freda L. Wolfson, U.S.D.J.

We hereby consent to the form and entry of this Order:

Dated: September 21, 2020

By: s/ William C. Baton
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